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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/783,254

02/13/2001

Motasim Sirhan

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05/12/2006

TOWNSEND AND TOWNSEND AND CREW LLP  
AVANTEC VASCULAR CORPORATION (CLIENT # 20460)  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/783,254	SIRHAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-44, 46-51 and 60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-44, 46-51 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed February 2, 2006 have been fully considered but they are not persuasive. The applicant has argued that the claimed rate is not anticipated or obvious over Gregory (US 5,283,257). The applicant's reasoning is that Gregory's disclosed amount of drug is 10,000 fold the applicant's amount. The examiner disagrees. First, the amount of drug disclosed by Gregory is the amount of mycophenolic acid alone, not the amount of mizoribine (which is used with the mycophenolic acid in combination), therefore this argument is irrelevant to the claim. Second, the milligrams disclosed, is per kilogram of implant carrier, therefore, the actual drug amount present would be less than a millimeter, since a stent weighs nowhere near a kilogram. Third, the general conditions of the claim are present, a stent with mizoribine impregnated, therefore the rate at which it releases is not inventive since it would be obvious to optimize the already present conditions.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites the limitation "the matrix or barrier" in line 2. There is insufficient antecedent basis for this limitation in the claim. *Both* the matrix *and* barrier are not priorly recited in all claims 47, 48, and 49.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39-44, 48-49, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 5,283,257, cited previously). Referring to claims 60 and 39-41, Gregory discloses a method of inhibiting restenosis in a vessel comprising implanting a vascular prosthesis comprising a scaffold (stent impregnated with drugs; col.3, lines 48-53; col.8, lines 30-35) having means (impregnation means; thus may be portions of the stent that “impregnate” the drug) thereon for releasing mizoribine in the vessel, and releasing mizoribine (mizoribine is disclosed to be used in combination with other drugs; col.4, lines 17-31; col.6, lines 45-52, 59-63) from the prosthesis to inhibit smooth muscle cell proliferation, wherein substantial release of the mizoribine is delayed following implantation (inherently, there is some delay following implantation, since the drugs are disclosed to be “impregnated” within the stent, therefore, there will be some delay for the drug to reach or exit the surface of the stent). Although Gregory discloses testing different amounts of drugs until the optimum effect of the drug is reached (col.9, lines 6-15), Gregory does not expressly disclosed the exact rate claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed release rates, since wherein the general conditions of a claim are disclosed in the prior art (stent with impregnated mizoribine in an optimal amount for the desired implantation

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technique) it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 42-44, Gregory discloses mizoribine combined with mycophenolic acid (col.4, lines 17-31; col.6, lines 45-52, 59-63).

Referring to claims 48-49, Gregory discloses the drugs to be impregnated into the stent, therefore, portions of the stent act as a diffusion barrier for the drug.

Claims 39-44, 46-51, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US 6,071,305, cited previously) in view of Gregory et al. (US 5,283,257, cited previously). Referring to claims 60 and 42-44, Brown discloses a method of inhibiting restenosis in a vessel (col.4, lines 61-67) comprising implanting a vascular prosthesis comprising a scaffold (stent 11) having means thereon *for* releasing mizoribine in the vessel (release means may be considered openings 22, matrix 27, or membrane 34), and releasing a drug (23) from the prosthesis that inhibits smooth muscle cell proliferation (col.5, lines 6-17), wherein substantial release of the drug (23) is delayed following implantation (inherently, there is some delay following implantation, since Brown has disclosed the *same release means* as the applicant, such as biodegradable matrices, diffusion membranes, etc. therefore, Brown's drug inherently will react in the same manner as the applicant, since they both control the rate of release; basically, the drug will be delayed to get to the surface or exit the stent, because it takes time to travel through the diffusion barrier or for the degradable matrix to degrade or dissolve and inherently there will be a delay of release from the stent). Brown discloses use of drugs that inhibit restenosis and smooth muscle growth (col.4, lines 61-67; col.5, lines 6-17), however does not

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expressly discloses any of the specific drugs of this category, such as mizoribine or mycophenolic acid as claimed. Gregory teaches in the same field of drug delivery stents, that both mizoribine and mycophenolic acid are in the category of restenosis and smooth muscle cell growth prevention drugs (col.3, lines 60-64; col.4, lines 17-31; col.6, lines 45-52, 59-63), and additionally, which may be used with stents (col.3, lines 48-52; col.8, lines 31-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown's stent having restenosis and smooth muscle cell growth prevention drugs, with Gregory's teaching that mizoribine and mycophenolic acid are specific restenosis and smooth muscle cell growth inhibition drugs useful on vascular stents, to provide the stent with a particular drug of choice.

Further referring to claim 60 and 39-41, although Brown in view of Gregory discloses control of the rates by various means, in order to optimize the rate of release, Brown in view of Gregory does not expressly disclosed the exact rate claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed release rates, since wherein the general conditions of a claim are disclosed in the prior art (stent with impregnated mizoribine in an optimal amount for the desired implantation technique) it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 46-49, Brown discloses releasing drugs from a reservoir (20) or somewhere on the prosthesis by a degradable material/matrix (27; col.8, lines 61-67) or non-degradable matrix/barrier (pores in stent, col.7, lines 22-24; membrane 34, col.9, lines 10-17).

Referring to claims 50-51, Brown discloses applying the drug and matrix by the methods claimed (col.12, lines 37-47).

Claims 39-44, 46-51, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. (US 6,774,278, cited previously) in view of Gregory et al. (US 5,283,257, cited previously). Referring to claims 60 and 42-44, Ragheb discloses a method of inhibiting restenosis in a vessel (col.5, lines 38-42) comprising implanting a vascular prosthesis comprising a scaffold (stent 12) having means thereon for releasing mizoribine in the vessel (release means may be considered porous coatings 20, 24), and releasing a drug (18, 22) from the prosthesis that inhibits smooth muscle cell proliferation (col.5, lines 38-42), wherein substantial release of the drug (18, 22) is delayed following implantation (inherently, there is some delay following implantation, since Ragheb has disclosed the *same release means* as the applicant, such as biodegradable and diffusion coatings, etc. therefore, Ragheb's drug inherently will react in the same manner as the applicant, since they both control the rate of release; basically, the drug will be delayed to get to the surface or exit the stent, because it takes time to travel through the diffusion barrier or for the degradable coating to degrade or dissolve and inherently there will be a delay of release from the stent). Ragheb discloses use of drugs that inhibit restenosis and smooth muscle growth, particularly, the class of immunosuppressive agents (col.4, line 4), however does not expressly disclose any of the specific drugs of this category, such as mizoribine or mycophenolic acid as claimed. Gregory teaches in the same field of drug delivery stents, that both mizoribine and mycophenolic acid are in the category of restenosis and smooth muscle cell growth prevention drugs (col.3, lines 60-64; col.4, lines 17-31; col.6, lines 45-52, 59-

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63), and additionally, which may be used with stents (col.3, lines 48-52; col.8, lines 31-34).

Further, they are specific immunosuppressive agents (as admitted in applicants specification). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Ragheb's stent having restenosis and smooth muscle cell growth prevention drugs such as immunosuppressive agents, with Gregory's teaching that mizoribine and mycophenolic acid are specific restenosis and smooth muscle cell growth inhibition drugs (particularly immunosuppressive agents) useful on vascular stents, to provide the stent with a particular drug of choice.

Further referring to claim 60 and 39-41, although Ragheb in view of Gregory discloses control of the rates by various means (amount of drug, size of reservoir, porous coatings), in order to optimize the rate of release, Ragheb in view of Gregory does not expressly disclosed the exact rate claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed release rates, since wherein the general conditions of a claim are disclosed in the prior art (stent with impregnated mizoribine in an optimal amount for the desired implantation technique) it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 46-49, Ragheb discloses releasing drugs from a reservoir (see fig.5, 10A-10D) or somewhere on the prosthesis (as a layer) by a degradable material/matrix (col.3, lines 34-36) or non-degradable matrix/barrier (porous layer; col.3, lines 24-29; col.20, lines 22-31).

Referring to claims 50-51, Ragheb discloses applying the drug and matrix by the methods claimed (col.3, lines 53-60; col.4, lines 60-62; col.11, lines 64-67).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

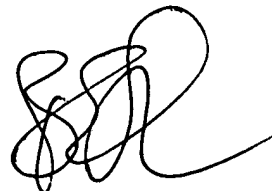
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



**BRUCE SNOW**  
**PRIMARY EXAMINER**